

## REMARKS

### Amendments to the Claims

Claim 1 is amended to recite that intranasal administration of a dendritic cell-tropic alphavirus vector. Support for dendritic cell-tropic alphavirus vector is at page 17, lines 4-10. Support for intranasal administration is at, for example, page 44 line 5 to page 45 line 13.

### Rejection of Claims 1, 5, 8-10, 13-15, 19-21, 29,30, 35-39, 41, and 42 Under 35 U.S.C. § 103(a)

Claims 1, 5, 8-10, 13-15, 19-21, 29,30, 35-39, 41, and 42 stand rejected under 35 U.S.C. § 103(a) as obvious over Malone<sup>1</sup> in view of Barchfield<sup>2</sup> as evidenced by Rappuoli.<sup>3</sup>

Malone is cited as teaching a method of inducing a mucosal immune response wherein an antigenic polynucleotide is administered to the vaginal, nasal or rectal mucosal membranes of a subject. Malone is also cited as teaching HIV as a source of antigenic polynucleotides, delivery of the polynucleotides by an alphaviral vector such as Sindbis or Semliki Forest Virus, and detoxified bacterial ADP-ribosylating toxins, including *E.coli* and cholera toxins. Barchfield is cited as teaching various detoxified bacterial toxins. The Office Action contends it would have been obvious to substitute the adjuvant of Malone with the adjuvants of Barchfield to enhance the immune response induced by Malone's composition, and that Rappuoli teaches detoxified bacterial ADP-ribosylating toxins would work as mucosal adjuvants. Office Action at page 7.

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<sup>1</sup> Malone *et al.*, U.S. Patent No. 6,110,898.

<sup>2</sup> Barchfeld *et al.*, WO 98/42375.

<sup>3</sup> Rappuoli, WO 95/17211.

A *prima facie* case of obviousness requires at least a suggestion of all limitations in a claim, *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)(citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)).

To advance prosecution, claim 1 is amended to recite intranasally administering a dendritic cell-tropic replication-defective alphaviral vector. None of the cited references, alone or in combination, teaches or suggests intranasal administration of a dendritic cell-tropic replication-defective alphaviral vector alone, much less such a vector in combination with a bacterial ADP-ribosylating toxin for intranasal administration.

The Patent Office has not made a *prima facie* claim of obviousness with respect to claim 1 and dependent claims 5, 8-10, 13-15, 19-21, 29,30, 35-39, 41, and 42. Applicants respectfully request withdrawal of the rejection.

#### Rejection of Claims 1 and 41 Under 35 U.S.C. § 103(a)

Claims 1 and 41 stand rejected as obvious over Malone, Barchfield, Rappuoli, and McCluskie.<sup>4</sup> McCluskie is cited as teaching CpG oligonucleotides to enhance immune responses alone and in combination with cholera toxin. However, McCluskie does not teach or suggest a dendritic cell-tropic replication-defective alphaviral vector and therefore does not cure the deficiencies of Malone, Barchfield, and Rappuoli described above. None of the references alone or in combination provide any reason to arrive at Applicants' claimed subject matter. The Office Action has not made a *prima facie* case that claims 1 and 41 are obvious.

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<sup>4</sup> McCluskie *et al.*, "Cutting Edge: CpG DNA is a potent enhancer of systemic and mucosal immune responses against hepatitis B surface antigen with intranasal administration to mice." J. Immunol. 1998 161:4463-4466.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,  
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